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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,694	KEVY ET AL.	
	Examiner	Art Unit	
	LAURA SCHUBERG	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009 and 29 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed on 10/15/2009 and 01/29/2010.

Claims 19-20 have been canceled and claims 1, 21 and 22 have been amended. No claims have been newly added.

Claims 1-18 and 21-22 are pending and have been examined on the merits.

Previous Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 11 recite the limitation "the precipitating agent" in line 1. There is insufficient antecedent basis for this limitation in the claim as claim 1 which they are dependent upon does not recite a precipitating agent.

Claims 14 and 15 recite the limitation "the coagulant" in line 1. There is insufficient antecedent basis for this limitation in the claim as claim 1 which it is dependent upon does not recite a coagulant.

Appropriate correction is required.

For examination purposes the claims are interpreted as the precipitating agent being the ethanol or ethanol mixture added in step (b) and the coagulant is interpreted as the thrombin preparation produced in step (e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 3, 7-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (US 4,680,177) in view of Cochrum et al. (US 5,773,033).

Amended claim 1 is drawn to a method for the production of thrombin from anticoagulated whole blood for the formation of a wound healing material comprising:

a) obtaining a volume of anticoagulated whole blood from a subject;

b) mixing the anticoagulated whole blood with ethanol;

c) incubating the mixture of b) at room temperature for a time sufficient to produce cellular and specific plasma component precipitate and a supernatant;

d) separating the precipitate from the supernatant;

e) recovering the supernatant wherein the supernatant contains a thrombin preparation comprising 80-90% of prothrombin-thrombin proteins, no detectable fibrinogen and 20-30% of baseline levels of anti-thrombin III (ATIII).

Claim 2 includes wherein the volume of anticoagulated whole blood is between 8 to 10 ml.

Claim 3 is drawn to wherein the whole blood is anticoagulated with an anticoagulant selected from the group consisting of ACD, ACD/mannitol, CPD, and EDTA.

Claim 7 includes wherein the precipitating agent is ethanol.

Claims 8-10 include wherein the ethanol used is at a starting concentration of about 10% to 100%, about 25% to 95%, about 50% to 95% respectively.

Claim 11 includes wherein the precipitating agent is a mixture of ethanol and calcium chloride.

Claims 12 and 13 include wherein the incubation step requires less than 45 minutes and 30 minutes respectively.

Claim 14 includes wherein the coagulant prepared is autologous.

Claim 15 includes wherein the coagulant prepared is homologous.

Gray et al. teach a method for the production of blood products wherein anticoagulated whole blood or blood plasma is processed by cryoprecipitation to yield a precipitate that is separated from the supernatant (column 4 lines 39-49). While blood plasma is indicated as preferred over whole blood (column 4 lines 9-21), whole blood is clearly indicated as an option (column 4 line 39 and column 8 lines 45-58). Anticoagulation with neutral salts is indicated as preferred when coagulant activity in the precipitate is desired (column 4 lines 39-50), the use of anticoagulants such as CPD, ACD or EDTA are indicated as less preferred options since they leave more coagulant activity in the remaining supernatant (column 4 line 1-57), and are used for comparisons (column 8 lines 45-58). Blood is taken from a mammalian donor (homologous) (column

3 lines 55-60). Calcium chloride is taught as a possible option as an anticoagulant (column 6 lines 37-40). The coagulant produced is intended for administration to a patient for the induction of clotting (column 1 lines 19-24) and is therefore inherently combined with the blood (as well as the blood derivatives) of the patient to obtain a clot.

Gray et al. do not teach the mixing of the anticoagulated whole blood with a precipitating agent, wherein the volume of anticoagulated whole blood is between 8 to 10 ml, or wherein the coagulant is autologous.

Cochrum et al. teach that suitable methods of precipitation of blood in order to obtain an adhesive agent include cryoprecipitation or precipitation by using ethanol (column 2 lines 15-25). Cochrum et al. also teach that it is preferable when producing blood products to use the patient's own blood in order to eliminate or reduce the risk of disease transmission or immunoreactions caused by introduction of foreign proteins (column 2 lines 41-55).

Therefore, one of ordinary skill in the art would have been motivated to substitute different methods of precipitation (such as ethanol precipitation) for cryoprecipitation in the method of Gray et al. with a reasonable expectation of success because Cochrum et al. teaches that these are art recognized equivalents for forming precipitates from blood for the purpose of obtaining adhesive agents. Since Cochrum et al do not require a specific temperature for the precipitation methods of the adhesive agent, one of ordinary skill in the art would have been motivated to use room temperature as this would have simplified the methods by not requiring steps for heating or cooling.

The amount of whole blood and ethanol used and the length of time for incubation would have been a matter of routine optimization depending on the final amount of coagulant or blood component needed. One of ordinary skill in the art would have been motivated to use the smallest amount of blood possible when drawing from the same patient to minimize blood loss during surgery. One of ordinary skill in the art would have used the shortest incubation time in order to supply the coagulant or blood component to the patient as quickly as possible.

One of ordinary skill in the art would have been motivated to use autologous blood in the method of Gray et al. with a reasonable expectation of success because Cochrum et al. teaches that autologous blood is preferable to reduce disease transmission (column 2 lines 50-55).

As far as the new limitations regarding the purity of the final thrombin product, these claim limitations are descriptions of the final product achieved using the obvious method steps of the claimed invention and are therefore deemed to be the inherent result of following those steps that have been deemed to be obvious. If this is not the case it would be appear that the claimed invention must be missing essential method steps to ensure such a final product. In addition the purification and optimization of the final product of thrombin to remove or reduce inhibiting proteins would have been an obvious modification as well.

Therefore, the combined teachings of Gray et al. and Cochrum et al. render obvious Applicant's invention as claimed.

Claims 1-4, 7-18 and 21-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coelho et al. (US 6,472,162) in view of Rock (US 4,359,463).

Claim 4 is drawn to wherein the whole blood is anticoagulated with ACD.

Claim 16 includes wherein the separating step is centrifuging the mixture.

Claim 17 includes wherein the separating step is by filtering the mixture.

Claim 18 includes wherein the separating step is a combination of centrifugation and filtration of the mixture.

Claim 21 includes wherein the blood derivative is chosen from a group to obtain a wound healing composition.

Amended claim 22 is drawn to a method for the production of a wound healing material consisting of:

a) obtaining a volume of anticoagulated whole blood from a subject;

b) mixing the anticoagulated whole blood with ethanol at room temperature;

c) incubating the mixture of b) at room temperature for a time sufficient to produce cellular and specific plasma component precipitate and a supernatant;

d) separating the precipitate from the supernatant;

e) recovering the supernatant wherein the supernatant contains a coagulant and is in a form suitable for application as a wound healing material.

Coelho et al. teach a method for extracting and then dispensing thrombin consisting of taking whole blood from a person, sequestering prothrombin from the

whole blood by addition of ethanol (mixing, incubating, and collecting), wherein ethanol is present at a concentration between 8% and about 20% and converting prothrombin to thrombin (column 12 claim 17). Filtering is used to separate the precipitate from the supernatant and calcium chloride is added with the ethanol (column 10 lines 7-49) however both filtering and centrifugation are taught as suitable methods for separating precipitate from supernatant (column 9 lines 13-17). Wherein the coagulant prepared is autologous is specifically taught (column 6 line 46) as well as sourced from a single donor (homologous) (column 6 line 11). Coelho et al also teach wherein the coagulant is combined with the clotting and adhesive proteins (blood derivatives) harvested and concentrated from the same unit of blood to form a biological sealant (column 5 lines 60-65). While Coelho et al. are silent with regard to the amount of whole blood required; the apparatus used for the method is capable of receiving a volume of 15 ml (column 9 line 42). The incubation time is taught at about 60 minutes or 30 to 75 (column 10 lines 27 and 42). Coelho et al are also silent to what temperature is used in the embodiments wherein the whole blood is precipitated, but one of ordinary skill in the art would have been motivated with a reasonable expectation of success to use room temperature since this is the temperature that is used in the other embodiments utilizing precipitation agents (column 11 lines 5-39). Wherein the method consists of only precipitating whole blood with ethanol in a manner sufficient to produce an adhesive agent and separating the agent from the rest of the composition is included as well (column 6 lines 28-34 and column 12 claim 17).

Rock teaches a method of treating whole blood to obtain Factor VIII and that whole blood that is withdrawn from a patient is generally collected with an anticoagulant (column 1 lines 14-17). Commonly used anticoagulants include ACD, CPD and EDTA (column 2 line 63 – column 3 line 6).

While the addition of an anticoagulant is considered to be inherent to the method of Coelho et al. as described in the previous office action, even if it had not been inherent, it would have been obvious for one of ordinary skill in the art to add the anticoagulant to the whole blood in the method of Coelho et al. The artisan of ordinary skill would have been motivated with a reasonable expectation of success by the fact that it was common practice to add anticoagulants to blood collected for the purpose of obtaining blood products as taught by Rock.

Coelho et al. does not teach the amount of whole blood to be used, higher concentration levels of ethanol, or incubation times of less than 30 minutes. However these variables would have been a matter of routine optimization depending on the final amount of coagulant needed. One of ordinary skill in the art would have been motivated to use the smallest amount of blood possible when drawing from the same patient to minimize blood loss during surgery. One of ordinary skill in the art would have used the shortest incubation time in order to supply the coagulant or blood component to the patient as quickly as possible. One of ordinary skill in the art would have optimized the concentration of the ethanol to obtain a product of the highest amount with the highest purity in the shortest amount of time possible. One of ordinary skill in the art would have been motivated to use both centrifugation and filtering to separate the precipitate from

the supernatant in order to improve the quality and purity of the final product. One of ordinary skill in the art would have had a reasonable expectation of success because Coelho et al. do suggest that modifications and adaptations of the method may be applied to the method as needed (column 11 lines 34-39).

As far as the new limitations regarding the purity of the final thrombin product, these claim limitations are descriptions of the final product achieved using the obvious method steps of the claimed invention and are therefore deemed to be the inherent result of following those steps that have been deemed to be obvious. If this is not the case it would be appear that the claimed invention must be missing essential method steps to ensure such a final product. In addition the purification and optimization of the final product of thrombin to remove or reduce inhibiting proteins would have been an obvious modification as well.

Therefore, the combined teachings of Coelho et al. and Rock render obvious Applicant's invention as claimed.

Claims 5 and 6 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coelho et al. (US 6,472,162) in view of Rock (US 4,359,463) as applied to claims 1-4, 7-18 and 21-22 above, and further in view of Sato et al (US 4,812,310).

Claim 5 includes wherein the anticoagulant is ACD/mannitol.

Claim 6 includes wherein the mannitol is present in a concentration of 7.5 mg/ml ACD.

The combination of Coelho et al. and Rock teach the invention of claims 1-4, 7-18 and 21-22 as described above, but do not specifically mention that mannitol is to be used in combination with ACD.

Sato et al. teaches that by adding mannitol to blood, the swelling of blood cells can be prevented during the preservation (column 4 lines 32-34). Sato et al. teach that it has been found that by adding mannitol to a conventional preserving solution such as ACD that the concentration depends on the amount of blood to be preserved, the decrease in Na+ concentration and the increase in K+ concentration in the plasma for the hemolysis to be prevented (column 4 lines 40-50). Sato et al. teach that mannitol was usually added in an amount of 0.67 to 6.7 w/v% (column 5 line 66).

One of ordinary skill in the art would have been motivated to add mannitol to the ACD anticoagulant in the method of Coelho et al because Sato et al. teaches that by adding mannitol to blood, the swelling of blood cells can be prevented during the preservation (column 4 lines 32-34). One of ordinary skill in the art would have had a reasonable expectation of success because Coelho et al. do suggest that modifications and adaptations of the method may be applied as needed (column 11 lines 34-39) and Sato et al. teach that this modification is applicable to the preservation of a blood preparation, particularly whole blood (column 6 lines 30-35).

The concentration of mannitol used with ACD in the method of Coelho et al. would have been a matter of routine optimization. One of ordinary skill in the art would

have been motivated to adjust the level of mannitol since Sato et al. teach that the concentration depends on the amount of blood to be preserved, the decrease in Na+ concentration and the increase in K+ concentration in the plasma (column 4 lines 40-50). One of ordinary skill in the art would have had a reasonable expectation of success because Sato et al. teach a range of concentrations for optimization (column 5 line 66).

Therefore, the combined teachings of Coelho et al., Rock and Sato et al. render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 10/15/2009 and 01/29/2010 have been fully considered but they are not persuasive.

The Mandle declaration under 37 CFR 1.132 filed 01/29/2010 is insufficient to overcome the rejection of claims 1-18, 21 and 22 based upon Gray et al in view of Cochrum and Coelho et al in view of Rock as applied under 35 U.S.C. 103(a) as set forth in the last Office action because: the facts presented are not germane to the rejections at issue as the declaration is directed to the office action dated December 15, 2007 and addresses arguments to the obviousness rejection in view of McGinnis (US 2004/0120942). The most recent office action recites obviousness rejections based upon totally different references and therefore the statements made in the Mandle declaration do not relate to the current rejections and are insufficient to overcome these newer rejections.

Applicant argues that with regard to the teachings of Gray and Cochrum that one of skill in the art would not be likely to substitute a chemical method of precipitation for cryoprecipitation. Applicant asserts that freezing and thawing is a gentler treatment than chemical precipitation with an agent such as ethanol.

This is not found persuasive because Cochrum clearly teaches that both cryoprecipitation and ethanol precipitation are suitable for the sequestering of an adhesive agent such as prothrombin and thrombin (column 2 lines 15-25).

Applicant argues that the teachings of Cochrum relate to the preparation of purified fibrinogen and are therefore completely inapposite to Applicant's method as currently claimed which seeks to produce thrombin that is virtually free of fibrinogen. Applicant asserts that one cannot extrapolate a method for one protein to another unrelated protein. Applicant asserts that one of ordinary skill in the art would not have had a reasonable expectation of success in combining the teachings of Cochrum and Gray to achieve Applicant's invention as currently claimed.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The disclosure of Cochrum et al is drawn to the making of hemostatic agents from human blood which puts it in the same field of endeavor as Gray et al which is also drawn to the making of hemostatic agents from blood. Cochrum et al specifically states

that the production of a blood fraction used as an adhesive agent may be obtained by cryo-precipitation or by precipitation with ethanol, centrifugation or ammonium sulfate. Clearly the precipitation of fibrinogen, which leaves behind the prothrombin fraction in the supernatant, is known to be achieved by several different suitable precipitation methods in the prior art. Clearly Cochrum et al suggest that these precipitation methods are equivalents in the art of obtaining hemostatic agents from a patient's own blood and that any one of them would be considered acceptable alternatives (column 2 lines 15-25). In addition Coelho et al demonstrate that ethanol can be used to precipitate either a plasma fraction or whole blood to produce a hemostatic agent thus suggesting that if the precipitating agent works for one sample type it will work for the other as well.

Applicant argues that the Coelho et al embodiment utilizing whole blood as the starting material is not enabled by the disclosure of Coelho et al. Applicant asserts that specification of Coelho et al contains no guidance from which one skilled in the art, using knowledge of whole blood and its fractionation, would conclude that whole blood and plasma are interchangeable in the Coelho et al method. Applicant asserts that the submitted evidence (including the 132 declaration, the article by ThermoGenesis, and the brochure for the device used by Coelho et al) prove that the Coelho et al method was not enabled with regard to using whole blood.

This is not found persuasive because the claimed invention of Coelho et al has in fact been patented (US 6,472,162), and thus the Office has determined that the method of Coelho et al is in fact enabled with respect to whole blood. In addition the fractionation of whole blood by precipitating proteins is known in the prior art as

demonstrated by the teachings of Xiao et al and Gray et al (both cited in previous and current rejections) as well as by Demopoulos et al (page 305, column 2, lines 13-17), Weissbach et al (page 808, 2nd paragraph) and Meucci et al (US 5,135,875 column 6 lines 29-32). Clearly the fractionation of whole blood by precipitation is an alternative known in the prior art and thus the Coelho et al embodiment utilizing whole blood does not require additional teachings beyond what is provided in the specification of Coelho et al and the prior art to be considered enabled. While Applicant's claimed method may not be the standard method in the art, the prior art references cited in the 35 USC 103 rejections above clearly demonstrate that the claimed method is not nonobvious.

The declaration under 37 CFR 1.132 filed 06/14/2007 is insufficient to overcome the rejection of claims 1-18 and 21 based upon the references cited under USC 103 as set forth in the last Office action because: It include(s) statements which amount to an affirmation that the affiant has never seen the claimed subject matter before. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. The references cited in the USC 103 rejections clearly demonstrate that the claimed subject matter was known, suggested and considered in the prior art.

Applicant argues that the amendment to claim 1 requires that the resulting autologous thrombin contain 80-90% of prothrombin-thrombin proteins, no detectable fibrinogen and 20-30% of baseline levels of anti-thrombin III (AT III). Applicant asserts the claimed invention is non-obvious because none of the cited references teaches these characteristics.

This is not found persuasive because these claim limitations are descriptions of the final product achieved using the obvious method steps of the claimed invention and are therefore deemed to be the inherent result of following those steps that have been deemed to be obvious. If this is not the case it would be appear that the claimed invention must be missing essential method steps to ensure such a final product. In addition the purification and optimization of the final product of thrombin to remove or reduce inhibiting proteins would have been an obvious modification as well.

Applicant argues that Rock et al and Sato et al do not relate to the precipitation of either whole blood or plasma for the recovery of a coagulant material like thrombin. Applicant asserts that these references do not compensate for the deficiencies in the teachings of Coelho et al.

This is not found persuasive because the teaching of Rock et al was cited in the obviousness rejection to demonstrate that the anticoagulants claimed by Applicant are well known in the art and that their presence in the method of Coelho et al would have been obvious if not inherent. The reference of Sato et al was cited in the obviousness rejection to demonstrate that the advantages of adding mannitol to blood were well known in the art and that their addition to the method of Coelho et al would have been obvious due to these well known advantages. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In view of the foregoing, when all of the evidence is fully considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Laura Schuberg